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SALES hereby certify that annexed is a true copy of the Provisional specification
in connection with Application No. 2002952663 for a patent by WESTERN
SYDNEY AREA HEALTH SERVICE as filed on 14 November 2002.

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ORIGINAL

AUSTRALIA

Patents Act 1990

PROVISIONAL SPECIFICATION FOR THE INVENTION ENTITLED:

An Intramural Needle-tipped Surgical Device

Name and Address of Applicant:

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This invention is best described in the following statement:

An Intramural Needle-Tipped Surgical Device

Field of the Invention

- 5 **The present invention relates generally to medical equipment and procedures, and more particularly to catheter-type devices for treating the heart and other organs.**

Background

Radiofrequency (RF) ablation can successfully treat many cardiac arrhythmias.

- 10 Unfortunately, the depth of ablation lesions produced by conventional radiofrequency ablation is limited to 4-6 mm. Active cooling of the ablation electrode has been introduced in an attempt to increase lesion depth, but even ablation lesions produced by irrigated tip catheters may not be of sufficient depth to treat the critical site of some arrhythmias. Subsequent pathological examination of patients who had
- 15 unsuccessful radiofrequency ablation for intractable ventricular tachycardia revealed that the conventional, endocardial radiofrequency ablation lesion had not been transmural: e.g., see Palma, E. C. Saxenberg V, Vijayaraman P, Ferrick K, Gross J, Kim S, Fisher J, "Histopathological correlation of ablation lesions guided by noncontact mapping in a patient with peripartum cardiomyopathy and ventricular
- 20 tachycardia", *Pacing Clin Electrophysiol*, 24, 12, pp.1812-5.

- Radiofrequency ablation delivered through an intramural needle has been investigated as a possible means of producing true transmural ablation lesions: e.g., see Woo EJ, Tungjitkusolmun S, Cao H, Tsai JZ, Webster JG, Vorperian VR, Will JA, "A new
- 25 catheter design using needle electrode for subendocardial RF ablation of ventricular muscles: finite element analysis and in vitro experiments," *IEEE Trans Biomed Eng.* 2000, 47, pp. 23-31; and Kovoov P., "Radiofrequency ablation for ventricular tachycardia," Department of Medicine, Sydney, University of Sydney; 1997, p. 289 and Ohtake H, Misaki T, Matsunaga Y, Watanabe G, Takahashi M, Matsumoto I,
- 30 Kwawasuji M, Watanabe Y, "Development of a new intraoperative radiofrequency ablation technique using a needle electrode", *Ann Thorac Surg*, 58, 3, pp. 750-3.

Most needle ablation systems are designed for use during operative ablation, exposing the patient to the risks and discomfort associated with major cardiac surgery.

U.S. Patent No. 5,281,218 issued to Imran on 25 January 1994 describes a catheter having a needle electrode for RF ablation of human myocardium. The catheter is an elongate member with a lumen through the catheter lengthwise. A needle electrode is rigidly fixed to a terminal end of the catheter and is connected by a conductor passing through the lumen to an RF energy source. This U.S. patent also describes a further needle electrode disposed within the catheter that can be extended from and retracted into the catheter. A significant disadvantage of such catheter-based devices is that the needle electrode often cannot be positioned so that the catheter and hence the needle electrode are relatively perpendicular to the myocardium for insertion of the needle electrode into the tissue. Instead, the catheter and hence the needle electrode often contacts the myocardium at an acute or oblique angle. Firstly, the electrode for ablation may not be positioned at the desired location and because of the angle may slide along the surface. Further, if the needle electrode enters at an acute angle, the resulting lesion produced by RF ablation may not be sufficiently deep and may instead produce a longer, but shallower lesion. Thus, healthy tissue may be destroyed needlessly. Another disadvantage of this system is that any needle electrode of sufficient width to create a clinically useful ablation lesion (>4 mm width) requires considerable force to insert the needle into the myocardium. A catheter-based system is not able to deliver that force unless the catheter is fixed firmly to the myocardium. As shown in Figs. 7a and 7b, such a catheter-based system 700 has the disadvantage of the catheter tip 710 being forced away from the myocardium 730 during attempted insertion of the needle 720. Fig. 7a illustrates the catheter device ideally deployed with the catheter end 710 abutting the myocardial tissue 730; Fig. 7b shows how the catheter end 710 moves away from the myocardium 730 when an attempt is made to deploy the needle 720.

U.S. Patent No. 5,807,395 issued to Mulier et al on 15 September 1998 and International (PCT) Patent Publication No. WO 96/07360 published 14th March 1996 describe methods and apparatuses for RF ablation and hyperthermia using a hollow

needle electrode or helical electrode connected to a catheter to infuse conductive solution into the tissue to produce a larger virtual electrode and hence a larger treated area. A conductive fluid such as saline, saturated saline, or Ringer's solution is passed through the lumen of the catheter and is delivered via a port in the electrode at the end of the catheter into the tissue. In particular, this U.S. patent describes using a helical electrode for cardiac ablation. The helical electrode is screwed into the heart tissue by rotating the catheter body. That is, the helical electrode is screwed in and completely located within the tissue. The conductive solution is delivered via an opening at the end of the hollow electrode or via ports along the sides of the electrode.

10 This U.S. patent discloses screwing large electrodes into the tissue of depths from 5 mm to 15 mm, that is, deeply into the myocardial tissue. However, several significant disadvantages exist in this regard. Firstly, this catheter-based device has all of the disadvantages noted above in relation to U.S. Patent No. 5,281,218 regarding positioning of the catheter and the angle of attack of the electrode. That is, the

15 electrode may not enter the tissue perpendicular to the surface of the myocardial tissue. Further, the helical electrode can improperly damage or destroy substantially more tissue than is the case of a needle electrode in similar circumstances if the helical electrode is pulled from the myocardial tissue and rips away more tissue in the coils at depths of up to 15 mm. For example, this might result from defibrillating the

20 patient with the electrode in situ during a procedure. This could cause severe complications including cardiorespiratory arrest due to bleeding into the pericardial space.

U.S. Patent No. 6,251,121 issued to Saadat on 26 June 2001 describes apparatuses and methods for intraoperatively performing surgery to create transmural channels in tissue and in particular transmyocardial revascularisation. One apparatus described is a handheld device that includes a flexible hose with a cutting head coupled to a radiofrequency current source that uses low-pressure suction to stabilize an end region of the apparatus against tissue. This is done in an attempt to stabilize an end region of the device against a beating heart. Another stabilizing means comprises a corkscrew element disposed in a tubular member. The corkscrew element may be located on the

distal end of the shaft adjacent to the cutting head to pierce the epicardium and urge the cutting head in contact with the heart during the channel forming process.

U.S. Patent Nos. 5,447,533 and 5,531,780 issued to Vachon et al and Vachon on 5 September 1995 and 2 July 1996, respectively, describe a pacing lead having a stylet-introduced, anti-inflammatory drug delivery element that is advanceable from a distal tip electrode. The drug delivery element may serve to center an active fixation element, i.e. a helix, for active fixation of the lead in the myocardium. The pacing lead is described as including an advanceable helix or cork screw type active fixation means. The helix is usually retracted within the distal tip of the pacing lead, but can be extended from the distal tip of the pacing lead by pushing on a stylet. The user can screw the helix into myocardium by rotating the lead until the lead comes into contact with the myocardium. A dart capable of penetrating the myocardial wall is extended beyond the helix tip into the myocardium. The dart delivers therapeutic drugs to the area near the implanted tip of the helical electrode. While the helix in this configuration may be suitable for a pacing lead that does not need to be as accurately positioned within the heart chamber, this configuration is not satisfactory for an ablation catheter. During an ablation procedure, the catheter has to be carefully manipulated to a specific location in the heart, further rotation of the catheter is disadvantageous as this would displace the catheter from this location.

International (PCT) Patent Publication No. WO 99/22658 published 14 May 1999 (PCT/US98/23397 filed 3 November 1998) in the name of Scimed Life Systems, Inc. describes devices and methods for creating a series of percutaneous myocardial revascularization channels in the heart. A catheter is described that has an outer catheter shaft that includes an anchoring shaft and a treatment shaft or probe. The anchoring shaft has at its distal end an anchor, which has a pigtail or corkscrew configuration, and can anchor the catheter to the myocardium. The treatment shaft has a distal cutting tip and extends at an angle from the distal tip of the catheter so that the treatment shaft is separated from the anchoring shaft. As the treatment shaft is located some distance away from the site where the catheter is anchored, the treatment shaft is not in stable contact with the heart while the heart is contracting.

Additionally, the force required to deploy a large intramural needle is likely to bend the catheter as the anchoring shaft is located at an angle to the treatment shaft. As the anchoring and treatment shafts are located side by side within the outer lumen of the catheter, the anchoring and treatment shafts each have to be of a very small size to
5 allow the total diameter of the catheter to be small enough to be clinically useful. The constraints imposed on the size of the treatment shaft limits the diameter of the needle and hence reduces the ablation lesion diameter.

U.S. Patent Nos. 6,102,887 and 6,346,099 issued to Altman on 5 August 2000 and 12
10 February 2002, respectively, describe a catheter system for injecting therapeutic agents within a body tissue including the heart. A catheter includes a deployable distally penetrating structure that delivers agents within a heart wall. The penetrating structure is depicted to be a hollow helical needle for securing the delivery catheter to prevent misplacement that may result because of the motion of the beating heart. The
15 helical needle can be screwed into the tissue prior to delivery of a drug. Another penetrating structure incorporates a solid helix, and a hollow centrally located needle may be provided. However, this system suffers from the same disadvantages described above in relation to U.S. Patent No. 5,281,218 issued to Imran.

20 Thus, a need clearly exists for surgical equipment that can create thermal ablation lesions using a percutaneously or endoscopically delivered intramural needle to deliver electrical energy and that allows a user to steer a catheter to the area of interest and secure the catheter firmly to the myocardium with a fixation helix. The equipment must make efficient use of space to allow a maximum diameter needle to
25 be deployed.

Summary

In accordance with a first aspect of the invention, a surgical device for treating tissue is provided. The device includes:

30 an outer elongate member with a lumen formed therethrough;

an inner elongate member with a lumen formed therethrough, the inner elongate member disposed within the lumen of the outer elongate member and capable of rotation about a longitudinal axis of the inner elongate member;

5 a helical fixing member coupled at a distal end of the inner elongate member capable of extending from and retracting into the outer elongate member for screw-in type engagement with the tissue to connect a distal end of the outer elongate member with the tissue; and

10 a needle-like member disposed within a portion of the lumen of the inner elongate member capable of being extended from and retracted into an end of the elongate member, the needle-like member capable of being extended concentrically through the helical fixing member into the tissue.

The outer and inner elongate members may each be a catheter. Preferably, the needle-like member is hollow and is capable of delivering a liquid to irrigate the electrode tissue interface. The needle-like member may be an electrode.

15 Alternatively, the needle-like member may have one or more ring-like electrodes disposed circumferentially about the needle-like member. The device may include a conductor passing through the lumen of the inner elongate member and connected with the needle-like member for delivering electromagnetic energy to an electrode(s) for thermal ablation.

The helical fixing member may be made of metal.

25 The needle-like member may further include means for measuring the temperature of at least a portion of the needle-like member. Still further, the needle-like member may include means for measuring electrical activity from and pacing the nearby tissue through multiple ring-like electrodes attached to the exterior of the needle-like member.

30 The device may include an irrigation tube located within the needle-like member, wherein the needle-like member has at least one bore for releasing irrigation

liquid. Further, the device may include an ultrasound sensing device located within the needle-like member.

5 The device may further include a valve between the outer and inner elongate members, and a valve between the inner elongate member and the needle-like member. The device may further include a pull wire connected to a metal ring located at the distal portion of the catheter enabling the catheter to be flexed and deflexed as required.

10 In accordance with a second aspect of the invention, a surgical method for treating tissue is provided. The method includes the steps of:

positioning an outer elongate member with a lumen formed therethrough adjacent to the tissue to be treated;

15 providing an inner elongate member with a lumen formed therethrough, the inner elongate member disposed within the lumen of the outer elongate member and capable of rotation about a longitudinal axis of the inner elongate member;

twisting a helical fixing member coupled at a distal end of the inner elongate member capable of extending from and retracting into the outer elongate member for screw-in type engagement with the tissue to connect a distal end of the outer elongate member with the tissue for engagement with the tissue; and

20 deploying into the tissue a needle-like member disposed within a portion of the lumen of the inner elongate member capable of being extended from and retracted into an end of the elongate member, the needle-like member capable of being extended concentrically through the helical fixing member into the tissue.

25 The outer and inner elongate members may each be a catheter. Preferably, the needle-like member is hollow and is capable of delivering a liquid to irrigate the electrode tissue interface. The needle-like member may be an electrode. Alternatively, the needle-like member may have one or more ring-like electrodes disposed circumferentially about the needle-like member.

The method may further include the step of delivering the liquid via the needle-like electrode to irrigate the tissue.

The helical fixing member may be made of metal.

5

Preferably, the tissue is located in the heart or another organ that can be reached through the vasculature.

10 The method may further include the step of measuring the temperature of at least a portion of the needle-like member.

Preferably, a valve is provided between the outer and inner elongate members, and a valve is provided between the inner elongate member and the needle-like member.

15

Preferably, a pull wire connected to a distal metal ring is provided.

20 The method may further include the step of judging the depth that the needle-like member is to be inserted into the tissue using an ultrasound sensing device located within the needle-like member.

Brief Description of the Drawings

A small number of embodiments are described herein after with reference to the drawings, in which:

25

Fig. 1 is a side elevation view of an intramural, needle-tipped catheter for treating myocardial tissue in accordance with an embodiment of the invention;

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Fig. 2A is a detailed, side elevation view of the handle of the intramural, needle-tipped catheter of Fig. 1 (only a portion of the entire assembly of Fig. 1 is depicted);

Fig. 2B is a detailed, side elevation view of the handle of an intramural, needle-tipped

catheter with an attached syringe that may be practiced in another embodiment of the invention (only a portion of the entire assembly is depicted);

5 Figs. 3A, 3B, 3C, 3D, and 3E are detailed, side elevation views of needle tips that can be practiced with at least one of the catheters of Fig. 1 and 2 (only a portion of the entire assembly is depicted);

10 Fig. 4 is a detailed, side elevation view of the needle tip of the catheter of Figs. 1 and 3A (electrode rings not shown) with a helical fastening member deployed in myocardial tissue;

15 Fig. 5 is a detailed, side elevation view of the needle tip of the catheter of Figs. 1, 3A and 4 with the helical fastening member and the needle-like electrode deployed in myocardial tissue;

Figs. 6a-6d are schematic diagrams of the intramural, needle-tipped catheter in use for treating myocardial tissue in accordance with an embodiment of the invention; and

20 Figs. 7a and 7b are schematic diagrams illustrating deployment of an existing catheter-based system adjacent to myocardial tissue and displacement of the catheter-based system during deployment of a needle, respectively.

Detailed Description

25 A surgical device for treating tissue, a surgical method for treating tissue, and an intramural, needle-tipped catheter for treating tissue in the heart or other organs are described hereinafter. In the embodiments of the invention, a needle-like member may also be used for generating thermal lesions, removing tumors, and providing substances (e.g., stem cells suspended in a liquid) to the tissue, amongst other things. The description sets forth numerous specific details including catheter materials,
30 metals used for electrodes, and the like. However, it will be apparent to those skilled in the art that in the light of this disclosure numerous specific modifications and/or substitutions may be made without departing from the scope and spirit of the

invention. In other instances, details may not be expressed explicitly and have been omitted so as not to obscure the invention.

Fig. 1 is a side elevation view in cross-section of an intramural, needle-tipped device for treating myocardial tissue. The entire catheter 100 is not shown, as indicated by broken lines 110, to enable enlargement of the view of the tip of the catheter 100.

Fig. 2A provides an enlarged side-elevation view of the catheter handle 112, Fig. 2B provides an enlarged side-elevation view of another catheter handle capable of receiving liquid from a syringe, and Figs. 3A, 3B, 3C, 3D, and 3E provide enlarged, partial side-elevation views of needle tips 114. Figs. 2A and 2B do not depict the entire assembly of the device as the catheter tip and a large portion of the catheter are omitted to emphasise the handle construction. Likewise, Figs. 3A, 3B, 3C, 3D, and 3E do not depict the entire assembly of the device as the handle and a large portion of the catheter are omitted to emphasise the construction of the catheter tip and needle-like member. The catheter device 100 is described hereinafter with reference to Figs. 1-3.

Generating Lessons and/or Making Measurements

With reference to Fig. 1, the catheter shaft 116 includes an outer flexible body or sheath 120 with a connection to the catheter handle 112 at one end and a distal opening at the other end. The outer body or sheath 120 is constructed of suitable material such as plastic. A second flexible tube or torque sheath 122 is located within the outer body 120. The inner tube 122 is connected to the catheter handle 112 at one end and a helical fixing member or fastening needle 130 at the other end, as shown in Figs. 3A to 3E. The inner tube 122 is constructed of a suitable material, such as plastic, that allows the tube 122 to be flexible to deformation but still transmit torsional rotation to the helical fixing member or fastening needle 130 (for ease of description only, the helical fixing member or fastening needle is simply referred to as the "helical fastening needle" 130). The helical fastening needle 130 is connected to the tube 122 by an adhesive preferably. The helical fastening needle 130 has a sharp distal tip and a length of 2 mm. However, it will be appreciated by those skilled in the art that helical fastening needles or fixing members of different sizes may be practiced

without departing from the scope and spirit of the invention. The helical fastening needle 130 is made of a suitable material capable of fixing or fastening with tissue, such as stainless steel. The inner tube 122 and the attached helical fastening needle 130 are withdrawn or retracted into the outer body 120 so that the tube 122 and needle 130 are completely covered. An intramural needle-like member 124 can be located completely within the inner tube 122.

The intramural needle-like member 124 has a connection to a needle shaft 126 of Fig. 1, which extends back to the catheter handle 112. As shown in Fig. 2A, the needle shaft 126 in an embodiment of the invention may be coupled to an ablation wire 144 passing through the handle 112 for providing electromagnetic energy to the needle-like member 124 for thermal ablation of tissue. The electromagnetic energy may include radiofrequency (RF), microwave, or ultrasound energy. The ablation wire 144 may terminate in a 2 mm plug to enable the wire to be connected to an electromagnetic energy generator, e.g. a standard RF current generator. The needle-like member 124 may itself be an electrode for delivery of energy or have one or more electrodes in or on the needle-like member 124 for delivery of energy.

The needle-like member 124 has an inner lumen and a sharp distal tip to allow penetration of myocardial or other tissue. A temperature-sensing device may be located within the inner lumen or on the external surface of the needle-like member 124. Preferably, the temperature sensing device is a thermocouple 128, which is more preferably placed 3 mm from the distal tip of the needle-like member 124. The thermocouple 128 is connected to two wires 132 that extend proximally through the catheter handle 112. The wires 132 preferably terminate in 2 mm plugs to enable temperature monitoring during thermal tissue ablation.

Pressure valves 190 are located between the inner and outer tubes 122, 120 and between the inner tube 122 and the needle-like member 124. The pressure valves 190 are shaped as hollow discs preferably made of an elastic material such as rubber. The pressure valves 190 are preferably attached to the exterior surface of the inner tube 122 and the exterior surface of the needle-like member 124. The pressure valves 190

allow axial and rotational movement of the inner tube 122 and the intramural needle-like member 124, but stop fluid or blood travelling back through the inner lumens of the catheter 100.

- 5 The needle-like member 124 can be extended and retracted in a controlled manner using the twistable handle shown in Fig. 2A. Thus the depth of insertion of the needle-like member into tissue can be controlled.

10 As shown in Fig. 3A, ring-shaped electrodes 170-173 are preferably located on the external surface of the needle-like member 124 in one embodiment of the invention to allow electrical activity within the tissue to be recorded at different depths. These electrodes 170-173 also enable the tissue around the needle-like member 124 to be paced. The ring-shaped electrodes 170-173 are constructed of a suitable conductor, preferably metal that is crimped or glued to the external surface of the needle-like member 124. The inner surface of the ring electrodes 170-173 are coated with an electrical insulator so that the ring electrode 170-173 is electrically isolated from the needle-like member 124. As shown in Fig. 3A, each electrode 170-173 has a respective wire 174-177 that is glued to the external surface of the needle-like member 124. The wires 174-177 preferably terminate in 2 mm plugs 178-181, as shown extending from the handle in Fig. 2A, to be connected to a standard electrophysiological recording system.

25 As shown in Fig. 3A, a fine bore irrigation tube or channel 134 is located within the lumen of the intramural needle-like member 124. Preferably, the irrigation tube 134 terminates 1 mm from the tip of the needle-like member 124. The other end of the irrigation tube 134 extends to the catheter handle 112 and terminates in a standard 'luer lock' intravenous fluid connection 136. More preferably, the needle-like member 124 includes one or more outlet holes or bores 138 to allow irrigation fluid to exit from the lumen of the needle electrode 124 and enter the circulation. In this embodiment, the outlet holes or bores 138 are located at least 5 mm proximal to the maximum insertion depth of the needle-like member so that the irrigation fluid is not expelled into the tissue being ablated. As shown in Fig. 1, a pull wire 142 is

connected at one end to a metal ring 140 attached to the inside of the outer catheter body 120 and at the other end to a lever 148 on the catheter handle 112. Manipulation of the lever 148 enables the distal catheter tip to be flexed and deflexed to facilitate catheter placement.

5

The catheter handle 112 also has a sliding retraction/extension mechanism with a lever 146 coupled to a retraction spring 156 in an inner housing 150 within the handle 112. A pivotable elongated member 152 (preferably a screw) connects a rotatable attachment or dial 154 for the catheter to the body of the handle 112.

10

Another embodiment is shown in Fig. 3B, in which like features of Fig. 3A have the same reference number. The drawing has been simplified so as not to obscure details of this embodiment. For example, while ring electrodes are not depicted in Fig. 3B, the needle 124 may be practiced with such ring electrodes. An ultrasound crystal 160 is located at the distal portion of the internal lumen of the intramural needle-like member 124. The ultrasound crystal 160 is made of a suitable piezo-electric material. The ultrasound crystal 160 has a high resonant frequency, preferably greater than 10 mega Hertz to ensure that the crystal 160 is of minimal thickness. The ultrasound crystal 160 has a pair of conductive wires 161 connected to the crystal 160 that extend back to the catheter handle 112. The conductive wires 161 are connected to an ultrasound pulser/receiver to enable A mode images to be displayed from the crystal 160. During deployment of the intramural needle-like member 124 pulses of ultrasound energy are transmitted and received by the crystal 160. A suitable display instrument such as an oscilloscope can display the information received from the ultrasound crystal 160. For example, the thickness of the myocardium that the needle-like member 124 is in contact with can be measured from the oscilloscope display, because the epicardial surface of the heart is seen as an area of high ultrasound reflectivity. This improves the safety of the technique by allowing the operator to judge the depth that the needle-like member 124 should be inserted into the tissue. By avoiding over insertion of the needle-like member the risks of complications such as myocardial rupture, cardiac tamponade, and damage to the epicardial coronary arteries can be minimised in the given example.

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A further embodiment is shown in Fig. 3C in which the drawing has again be simplified so as not to obscure the details of this embodiment. Multiple small temperature sensing or measuring devices 194-197, preferably thermocouples, are
5 attached to the outer surface of the needle-like member 124. The temperature measuring devices 194-197 are spaced at regular intervals, preferably 2 to 5 mm. Sensing wires 193 can connect the temperature measuring devices 194-197 to a temperature analysis system. The temperature sensing devices 194-197 enable the operator to monitor the temperature response at a variety of tissue depths. During the
10 ablation procedure, the temperature measuring devices 194-197 located within the tissue (e.g., myocardium) show a temperature rise. The temperature measuring devices 194-197 that are outside of the tissue (e.g., myocardium) do not show a temperature rise during ablation as those temperature measuring devices 194-197 are cooled by the circulation of fluid (e.g., blood) past the devices. This results in
15 increased efficiency of the ablation procedure as the operator knows the exact depth of needle insertion by observing at which points in the needle-like member 124 the temperature increases during ablation.

Once the end of the catheter 100 has been steered to the area of interest, the operator
20 rotates the dial 154 on the handle 112. This rotation is transmitted to the inner torque sheath 122, advancing the helical fastening needle 130 up to 2 mm into the tissue (e.g., myocardium) 160 as shown in Fig. 4. After the helical fastening needle 130 has fixed the end of the catheter 100 against the tissue (e.g., myocardium), the operator can then advance the ablation needle electrode 124 into the tissue 160 to the required
25 depth as shown in Fig. 5. Electromagnetic energy (e.g. electrical current for RF energy) can then be delivered to the ablation needle-like member 124 and irrigation fluid can be circulated through the ablation needle-like member 124 at a suitable rate (e.g., 20ml/minute).

30 As depicted in Fig. 5, the helical fastening needle 130 extends preferably only up to 2 mm into the tissue (e.g., myocardium), while the needle-like member preferably extends up to 12 mm into the tissue. Other size needle-like members and helical

fastening needles may be practiced without departing from the scope and spirit of the invention. The irrigation fluid exits the needle-like member through the port 138 and may enter the surrounding fluid through the end of the catheter 100 abutting the tissue (e.g., myocardium).

5 Fixation of the end of the catheter 100 against the tissue 160 enables the ablation needle-like member 124 to be inserted into the tissue 160 easily and to be directed into the tissue at the correct angle. This is done by advancing or withdrawing the catheter 100 with the helical fastening needle 130 partially deployed. This technique
10 or process is illustrated by Figs. 6a-6d of the drawings.

Delivering Substances to Tissue

Fig. 2B is an alternate embodiment of the catheter handle shown in Fig. 2A. Features with the same reference numeral in Fig. 2B correspond to the like features in Fig. 2A,
15 and the corresponding description has not been duplicated to avoid repetition. In Fig. 2B, a syringe 195 is coupled to the 'luer lock' intravenous fluid connection 136. In this manner, substances may be delivered to tissue using the needle-like members in accordance with the embodiments depicted in Figs. 3D and 3E. For example, stem cells may delivered in a solution from the syringe 195 via the needle-like member to
20 the tissue.

Fig. 3D depicts a needle-like member having a closed terminal end (as per Figs. 3A, 3B, and 3C) but with an outlet bore or hole 138 adjacent the end of the needle-like member 124 to deliver the substance into tissue.

25 Fig. 3E depicts a needle-like member having an open terminal end 139 to deliver the substance into tissue in accordance with another embodiment of the invention.

Deployment of Device

30 Fig. 6a illustrates schematically a portion 620 of a catheter 600 of the type 100 depicted in Figs. 1-5 that is deployed near the area of interest 650 in myocardial tissue 610. The catheter tip contains a helical fastening needle 630 and a needle-like

member 640 retracted within the catheter and the tip is orientated obliquely to the ventricular wall.

Fig. 6b illustrates the helical fastening needle 630 advanced one turn allowing the helical fastening needle 630 to fix the catheter to the tissue (e.g., myocardium) 610 at one point. Further manipulation of the catheter 600 causes the catheter 600 to pivot at the fixed point. The operator advances the catheter 600 (as indicated by an arrow) to orientate the catheter tip perpendicularly to the ventricular wall, as shown in Fig. 6c.

Fig. 6d illustrates the intramural needle-like member 640 extended perpendicularly into the tissue 610 to fully cover the area of interest 650.

Preferably, the ablation needle-like member 124, 640 is irrigated with the irrigation fluid, which is then channelled into the circulation. This is done at a portal 138 at a distance away from the tip of the needle needle-like member 124, 640. If irrigation fluid were to be expelled from the tip of the needle, the irrigation fluid would be forced under pressure into the tissue (e.g., myocardium) 160, 610, leading to local swelling. Only small quantities of irrigation fluid could be delivered if the fluid were to be expelled into the tissue 160, 610, thereby limiting the ability of the irrigation fluid to effectively cool the ablation electrode 124, 640. Thus, the positioning of one or more portals 138 away from the portion of the needle to be placed in myocardial tissue is advantageous.

The embodiments of the invention have a number of advantages including the following. The embodiments of the invention enable fixation of the catheter to the tissue with a helical fastening needle. This is advantageous because the helical fastening needle can be moved independently of ablation needle-like member movement. This means that the helical fastening needle needs to be advanced only a few millimetres into the tissue to provide sufficient stabilisation for needle insertion. This is in marked contrast to catheters having a screw needle electrode for both fixation and ablation, which require the screw needle electrode to be inserted to a much greater depth. In the event of traumatic movement of the catheter (e.g., during

defibrillation) the helical fastening needle of the embodiments of the invention cause negligible damage to the tissue if dislodged since the helical fastening needle is only inserted 1-2 mm. Inserting a screw electrode as deep as the required ablation can disadvantageously lead to a large myocardial tear in the event of sudden movement of the screwed-in catheter. Thus, the embodiments of the invention have improved safety.

Further, the embodiments of the invention are advantageous in that the helical fastening needle can have a small outer diameter to enable it to enter the tissue (e.g., myocardium) with minimal resistance, relative to the larger diameter of screw electrodes that are required for ablation. This provides improved ease of use.

The embodiments of the invention are useful in a number of ways. Firstly, the embodiments can be used for ablation of ventricular tachycardia originating from intramyocardial and epicardial sites. Preliminary testing indicates that the percutaneous needle ablation catheter can create lesions of >12 mm of depth. Still further, the embodiments of the invention can be used for ablation of certain supraventricular arrhythmias where conventional ablation strategies have failed (eg atrial flutter). Still further, the embodiments of the invention can be used to provide thermal ablation therapy for cardiac or other tumours. Still further, the embodiments of the invention can be used to enable percutaneous ablation of non-cardiac tissue including but not limited to hepatic, renal and pancreatic tumours.

Thus, a surgical device for treating tissue, a surgical method for treating tissue, and an intramural, needle-tipped catheter for treating myocardial tissue have been described. While only a small number of embodiments have been set forth, it will be apparent to those skilled in the art that, in view of this disclosure, modifications and substitutions may be made without departing from the scope and spirit of the invention.

The claims defining the invention are as follows:

1. A surgical device for treating tissue, including:
5 an outer elongate member with a lumen formed therethrough;
an inner elongate member with a lumen formed therethrough, said inner
elongate member disposed within said lumen of said outer elongate member and
capable of rotation about a longitudinal axis of said inner elongate member;
a helical fixing member coupled at a distal end of said inner elongate member
10 capable of extending from and retracting into said outer elongate member for screw-in
type engagement with said tissue to connect a distal end of said outer elongate
member with said tissue; and
a needle-like member disposed within a portion of said lumen of said inner
elongate member capable of being extended from and retracted into an end of said
15 elongate member, said needle-like member capable of being extended concentrically
through said helical fixing member into said tissue.
2. The device according to claim 1, wherein said outer elongate member
20 is a catheter.
3. The device according to claim 1, wherein said inner elongate member
is a catheter.
- 25 4. The device according to claim 1, wherein said needle-like member is
hollow and is capable of delivering a liquid to irrigate the needle-like member.
5. The device according to claim 1, wherein said helical fixing member is
made of metal.

30

6. The device according to claim 1, further including a conductor passing through said lumen of said inner elongate member and connected with an electrode of said needle-like member for delivering electromagnetic energy for thermal ablation.

5 7. The device according to claim 6, further wherein said needle-like member further includes means for measuring the temperature of at least a portion of said needle-like member.

10 8. The device according to claim 6, further wherein said needle-like member further includes means for measuring electrical activity from and pacing the nearby tissue through multiple ring-like electrodes attached to the exterior of said needle-like member.

15 9. The device according to claim 1, further including an irrigation tube located within said needle-like member, wherein said needle-like member has at least one outlet hole for releasing irrigation liquid.

20 10. The device according to claim 1, further including an ultrasound sensing device located within said needle-like member.

11. The device according to claim 1, further including a valve between said outer and inner elongate members.

25 12. The device according to claim 1, further including a valve between said inner elongate member and said needle-like member.

13. The device according to claim 1, further including a pull wire connected to a metal ring attached to the distal portion of said outer elongate member.

30 14. The device according to claim 1, wherein said needle-like member has an outlet adjacent an end of said needle-like member for delivering a substance to the tissue.

15. The device according to claim 1, further including a plurality of temperature sensing or measuring devices attached said needle-like member and arranged at intervals to enable sensing or monitoring of temperature at a plurality of tissue depths.

16. A surgical method for treating tissue, said method including the steps of:

positioning an outer elongate member with a lumen formed therethrough adjacent said tissue;

providing an inner elongate member with a lumen formed therethrough, said inner elongate member disposed within said lumen of said outer elongate member and capable of rotation about a longitudinal axis of said inner elongate member;

twisting a helical fixing member coupled at a distal end of said inner elongate member capable of extending from and retracting into said outer elongate member for screw-in type engagement with said tissue to connect a distal end of said outer elongate member with said tissue for engagement with said tissue; and

deploying into said tissue a needle-like member disposed within a portion of said lumen of said inner elongate member capable of being extended from and retracted into an end of said elongate member, said needle-like member capable of being extended concentrically through said helical fixing member into said tissue.

17. The method according to claim 16, wherein said outer elongate member is a catheter.

18. The method according to claim 16, wherein said inner elongate member is a catheter.

19. The method according to claim 16, wherein said needle-like member is hollow and is capable of delivering a liquid to irrigate said needle-like member.

20. The method according to claim 16, further including the step of delivering said liquid via said needle-like member to cool the tissue electrode interface.

5 21. The method according to claim 16, wherein said helical fixing member is made of metal.

22. The method according to claim 16, wherein said tissue is located in the heart or another organ that can be reached through the vasculature, a hollow organ
10 such as the intestine or through a cavity such as but not limited to the peritoneal space or thoracic cavity.

23. The method according to claim 16, further including the step of delivering electromagnetic energy to said needle-like member for thermal tissue
15 ablation via a conductor passing through said lumen and connected with an electrode of said needle-like member.

24. The method according to claim 23, further including the step of measuring the temperature of at least a portion of said needle-like member.
20

25. The method according to claim 16, wherein a valve is provided between said outer and inner elongate members.

25 26. The method according to claim 16, wherein a pull wire attached to a metal ring located in the distal section of said outer elongate member is provided.

27. The method according to claim 26 further including the step of using the pull wire to flex and deflex the outer elongate member, enabling the outer elongate
30 member to be positioned at the region of interest.

28. The method according to claim 16, wherein a valve is provided between said inner elongate member and said needle-like member.

29. The method according to claim 16, further including the step of
5 judging the depth that said needle-like member is to be inserted into said tissue using an ultrasound sensing device located within said needle-like member.

30. The method according to claim 16, wherein said positioning step involves using a pull wire attached to a distal ring to flex and deflex said outer
10 elongate member as required.

31. The method according to claim 16, wherein said needle-like member has an outlet adjacent an end of said needle-like member for delivering a substance to the tissue.

32. The method according to claim 16, further including the step of
15 sensing or monitoring temperature at a plurality of tissue depths using a plurality of temperature sensing or measuring devices attached said needle-like member and arranged at intervals.

20
DATED THIS FOURTEENTH DAY OF NOVEMBER 2002
WESTERN SYDNEY AREA HEALTH SERVICE

25
PATENT ATTORNEYS FOR THE APPLICANT
SPRUSON & FERGUSON

An Intramural Needle-Tipped Surgical Device

Abstract

A surgical device (600) is described that is capable of creating deep thermal ablation lesions using a percutaneous or endoscopic technique. The device (600) has a catheter-like member (620) with a lumen that includes an intramural ablation needle (640) and a helical fixing member (630). The helical fixing member (630) is preferably 2 mm long and is used to fix the catheter (620) to the tissue to be ablated (610) enabling the intramural needle-like member (640) to be pushed into the tissue (610). The intramural needle-like member (640) may incorporate a thermocouple to allow temperature-controlled ablation and an irrigation tube to allow irrigated needle ablation.



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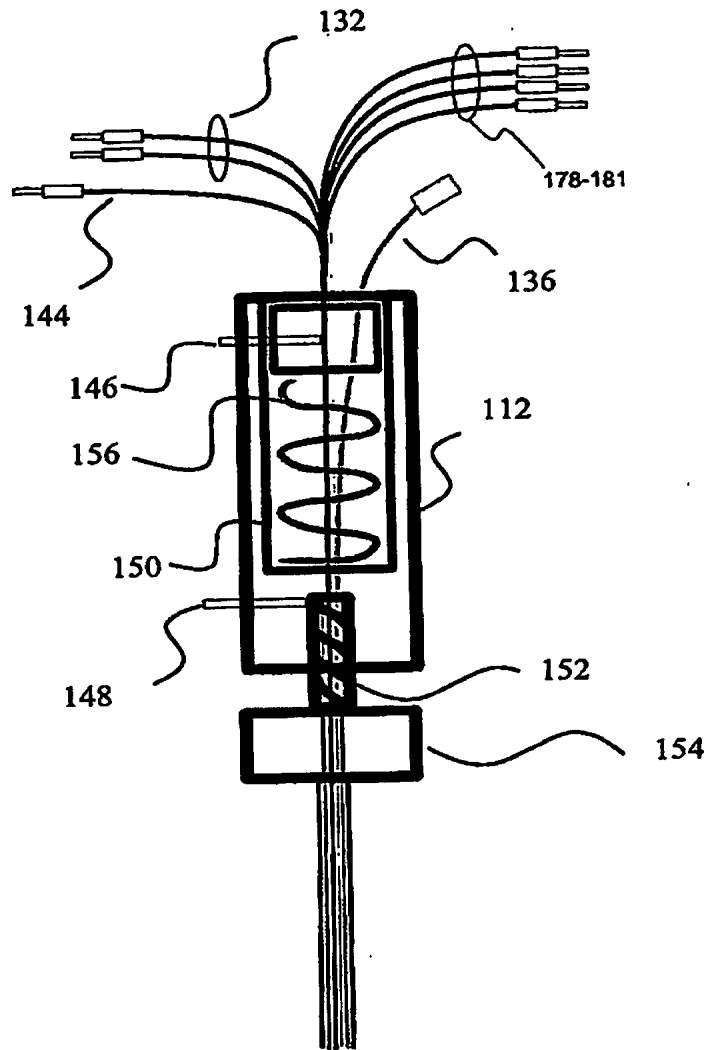


FIG. 2A

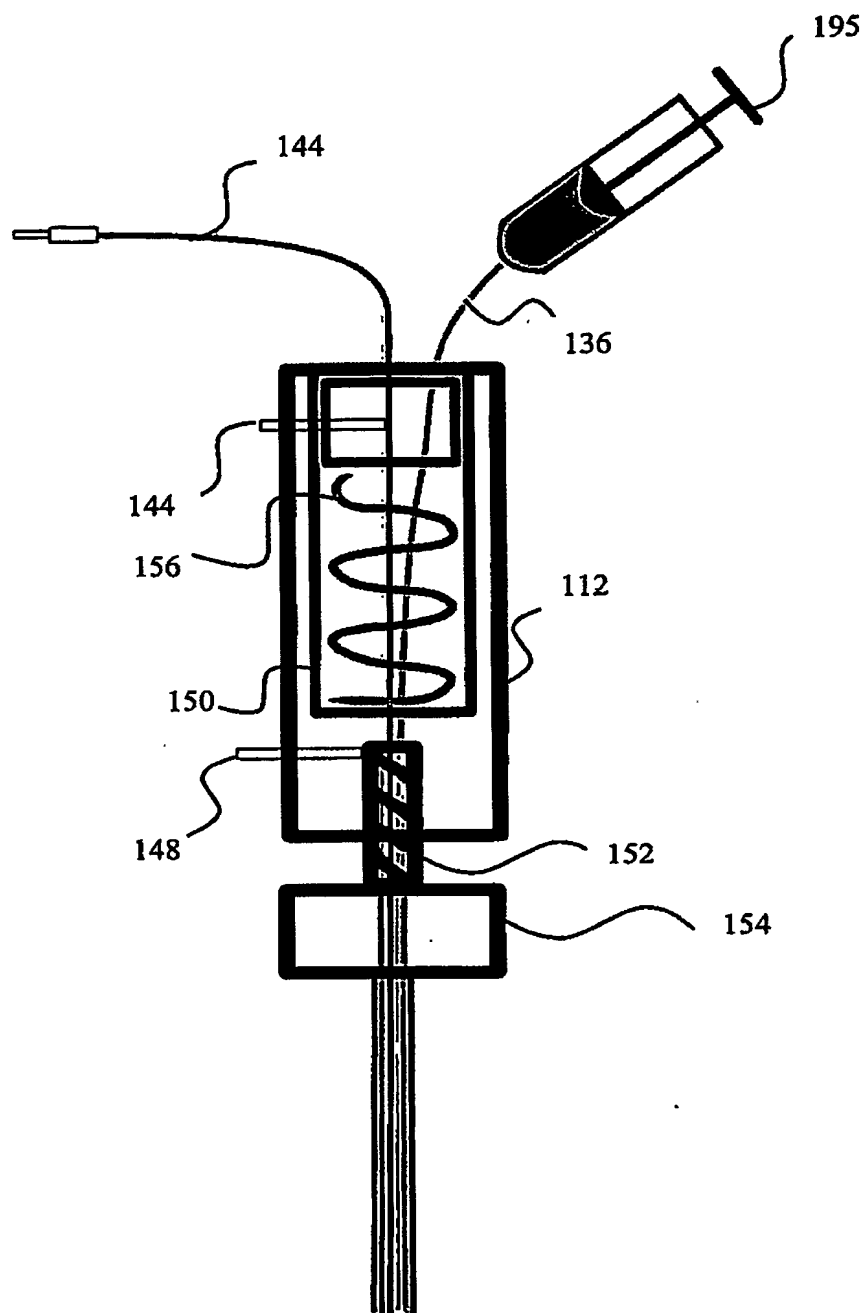


FIG. 2B

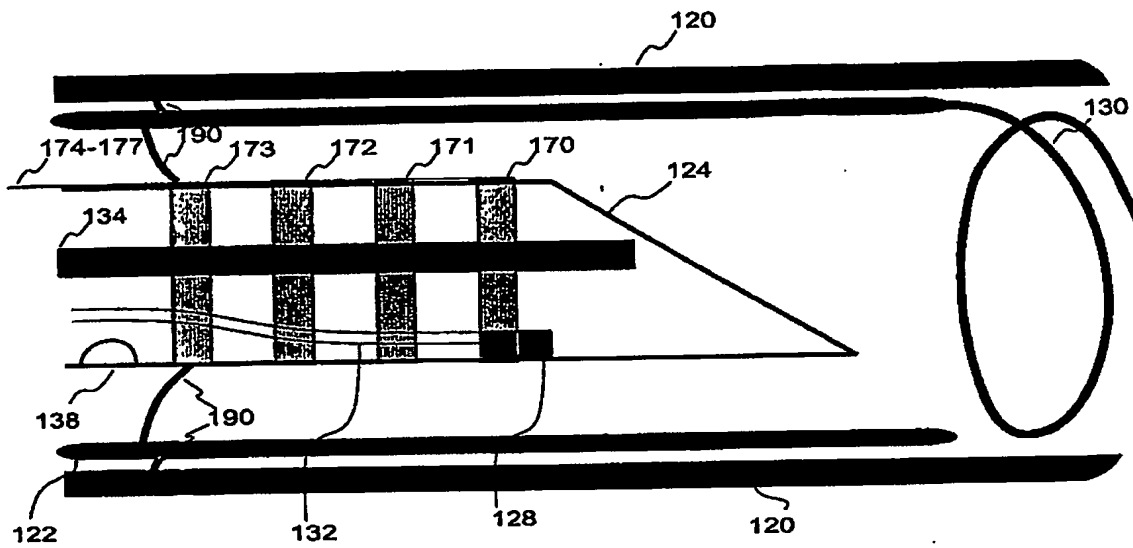


FIG. 3A

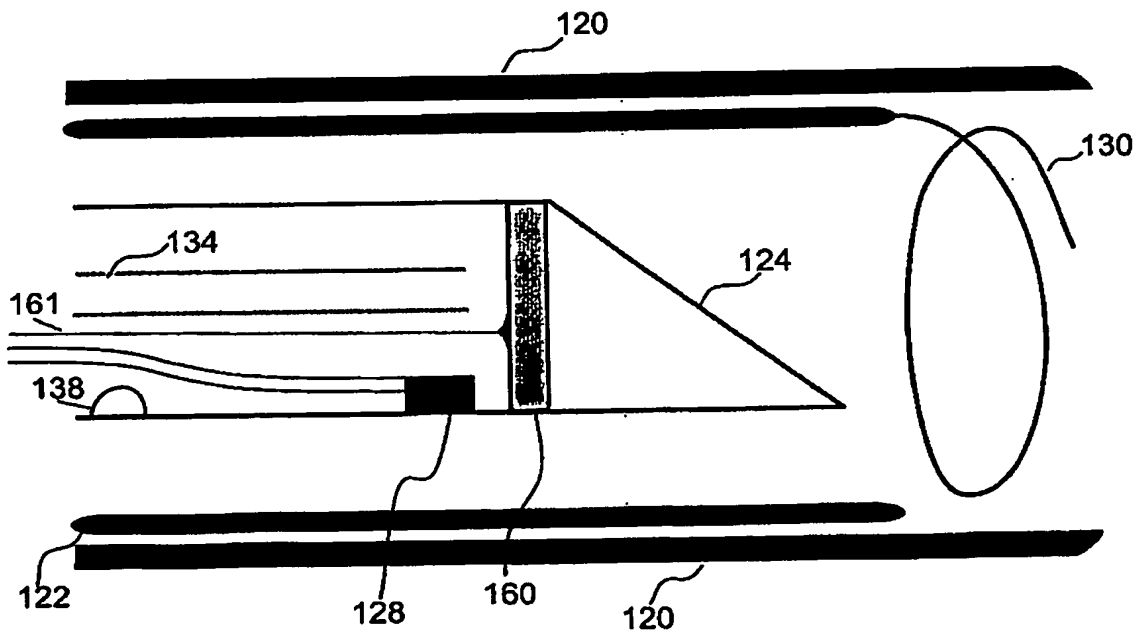


FIG. 3B

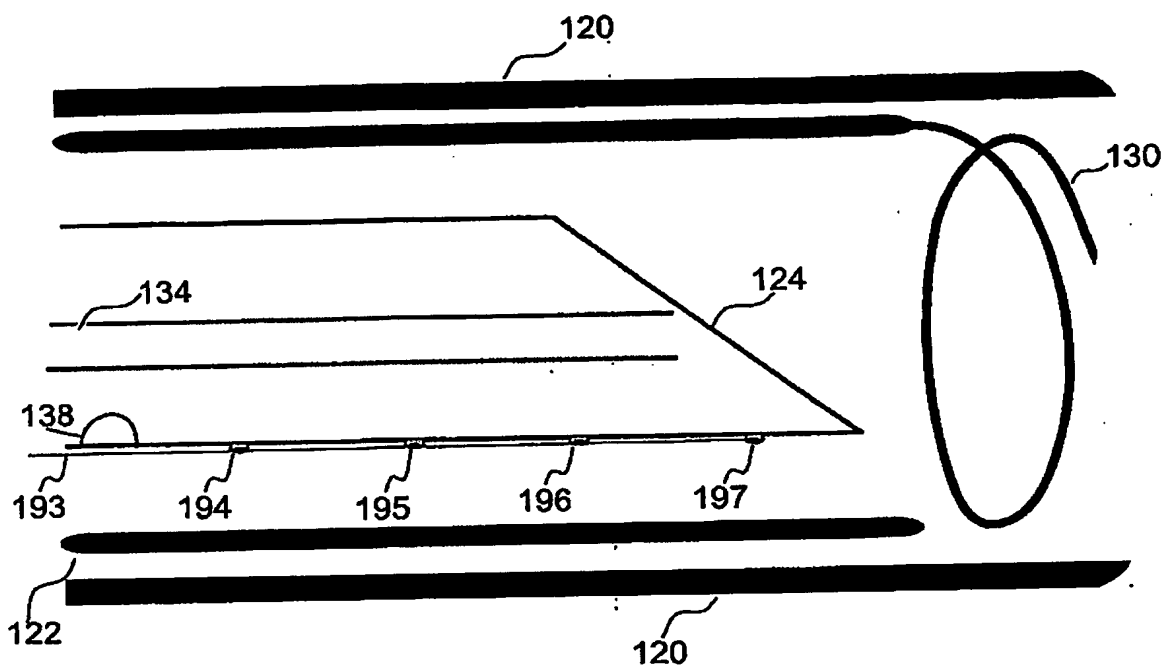


FIG. 3C

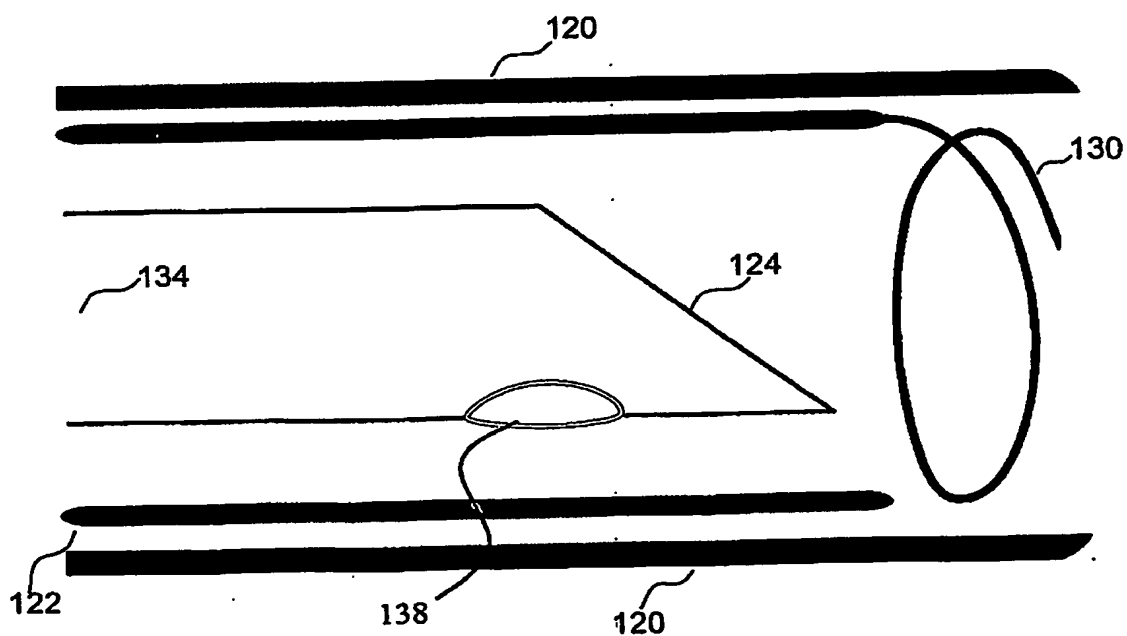


FIG. 3D

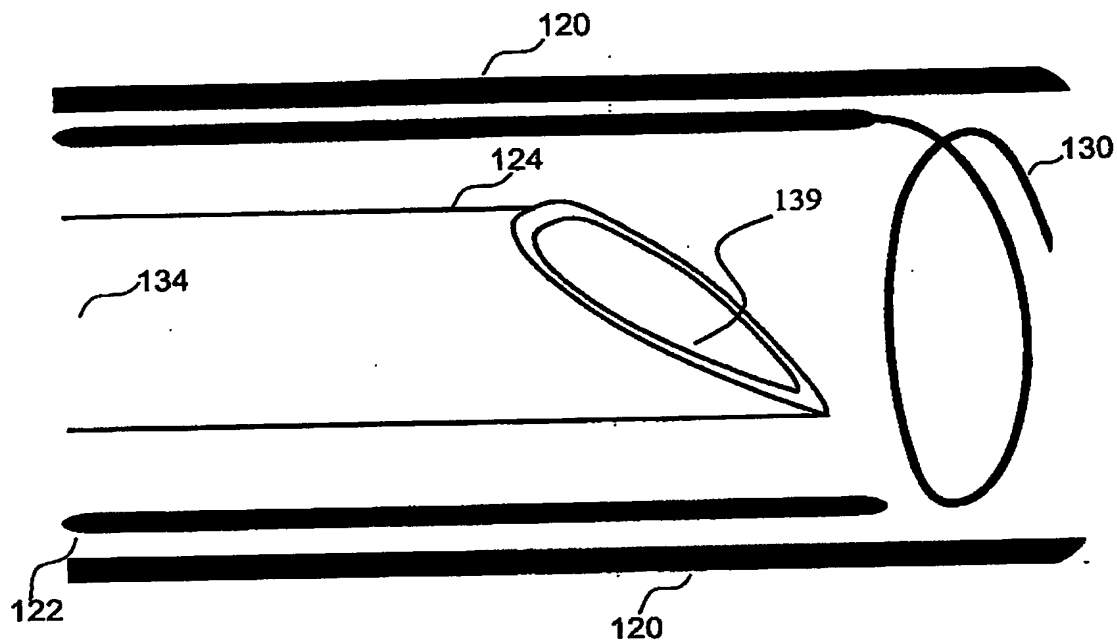


FIG. 3E

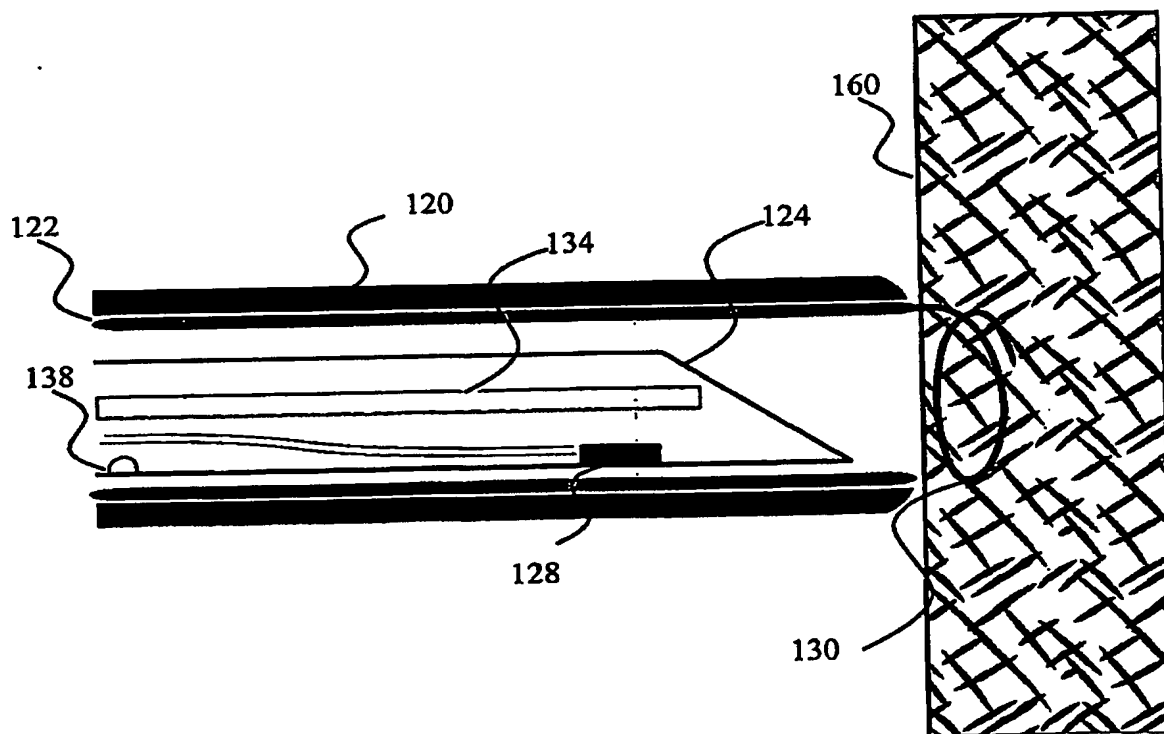


FIG. 4

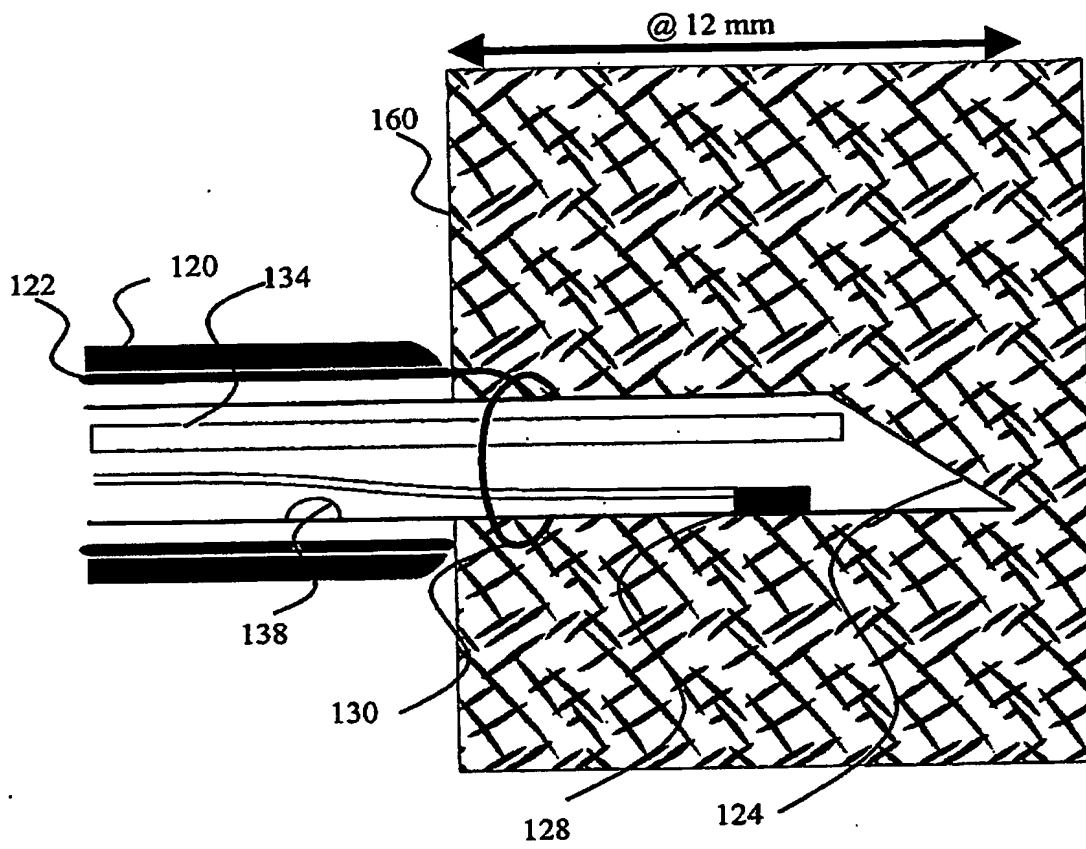


FIG. 5

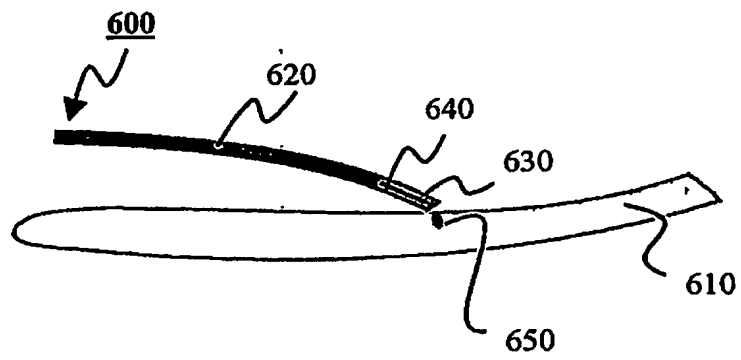


FIG. 6a

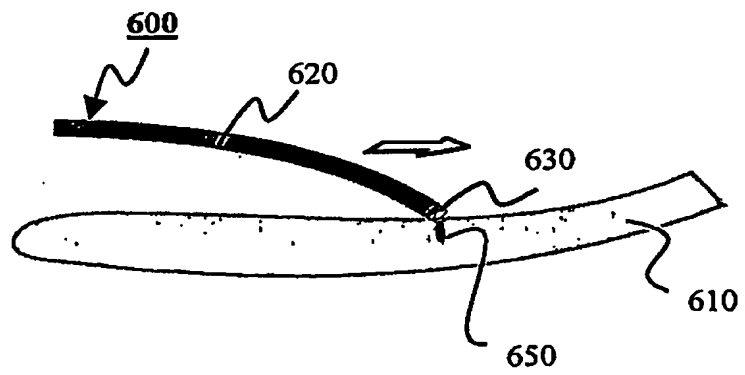


FIG. 6b

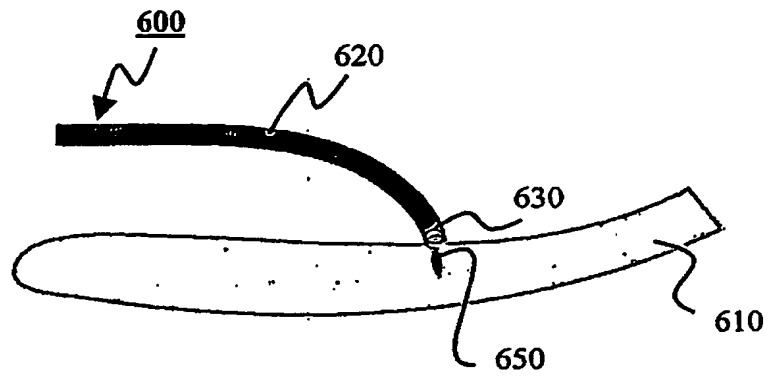


FIG. 6c

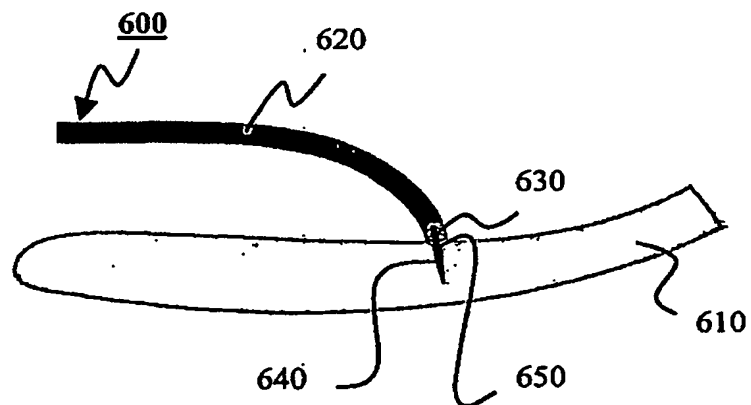


FIG. 6d

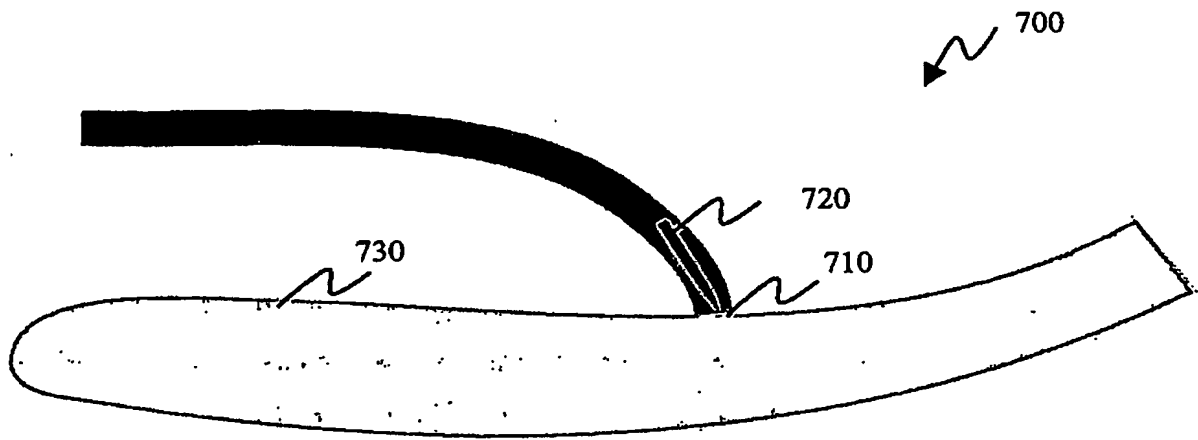


Figure 7a

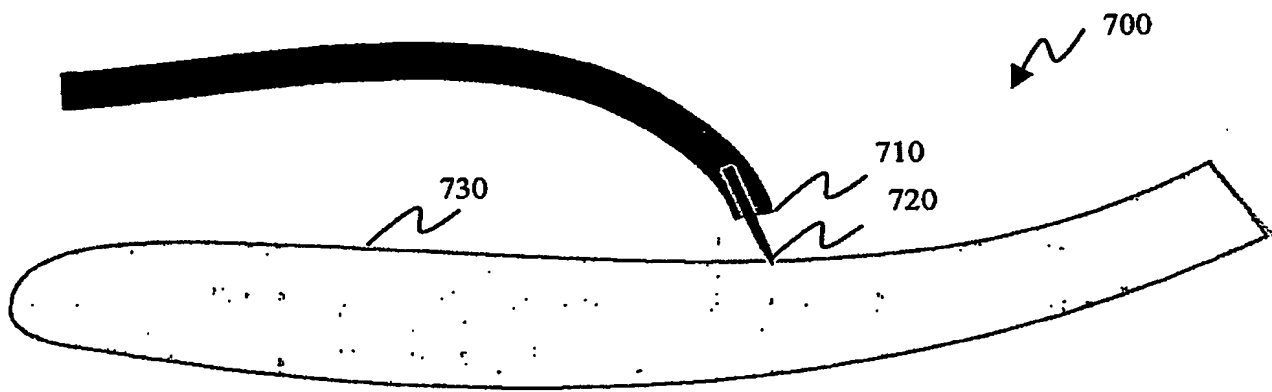


Figure 7b

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